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| 10/752,936 | 01/07/2004 | James Loyd | 930027-2022 | 5800 |
| 20999 | 7590 | 03/29/2006 | EXAMINER | |
| FROMMER LAWRENCE & HAUG 745 FIFTH AVENUE- 10TH FL. NEW YORK, NY 10151 | | | DIXON, ANNETTE FREDRICKA | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3743 | |

DATE MAILED: 03/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 10/752,936 | Applicant(s) LOYD ET AL. | |
| | Examiner Annette F. Dixon | Art Unit 3743 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 January 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. The amendment filed on February 2, 2006, has been entered. Examiner acknowledges that **Claims 1-21** are pending in this application, with **Claims 22-25** having been cancelled, and **Claims 1 and 12** having been amended.
2. Applicant's arguments filed on February 2, 2006, have been fully considered but they are not persuasive. Examiner acknowledges corrections to the specification, such as the naming of elements 22 and 28, to overcome objections to the specification. Regarding the naming of element 22, lesser thickness, to explain the two thicknesses associated with the second flange, it is still the belief of the Examiner that the drawings do not accurately show the two thicknesses to be consistent on both sides of the flange. In an effort to further support Examiner's assertions, the Examiner has obtained a draft person's review. Regarding the naming of element 28, oxygen supply source, Examiner acknowledges the flanges (12 and 14) are offset by 90 degrees. However, with out knowledge of element 28, the orientation of the device as well as the location of the patient was difficult to determine.
3. Applicant's arguments filed on February 2, 2006, have been fully considered but they are not persuasive.

Claim Objections

4. **Claims 2 and 13** are objected to because of the following informalities: Both claims read "first and second flanges are offset 90 0 from one another." Examiner

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suggests the Applicant write the word "degrees" or add a degree symbol, "°", between 90 and 0. Appropriate correction is required.

5. **Claims 2 and 13** are objected to because of the following informalities: Both claims read "...second thickness portion being smaller that the first." Examiner believes Applicant was attempting to recite "than that" or "than." Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. **Claims 1-21** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. No amendment may introduce new matter into the disclosure of an application after its filing date. See MPEP §608.04.

8. Specifically, **Claims 1-21** now recite the claim limitation "a first flange operable to be placed on the neck of a patient and having an opening therein"; however, the originally filed disclosure does not provide evidence that Applicant possessed the newly claimed invention at the time the application was filed. In fact, the original specification of the instant invention discloses "Still further examples of the prior art are directed at

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methods and devices for securing a tracheotomy tube to prevent its inadvertent removal from the stoma formed in the patient's trachea. Examples include U.S. Pat. Nos. 5,819,734, 5,782,236, and 6,105,577. In each of these examples there are described methods for securing the tracheotomy tube using straps which extend around the neck of the patient and attach to a flange section covering the stoma opening in the patients trachea." (See Paragraph 0009). Applicant is reminded "any negative limitation or exclusionary proviso must have basis in the original disclosure." See MPEP §2173.05(i). There is no specific recitation or support for "a first flange operable to be placed on the neck of a patient and having an opening therein"; in the specification as originally filed, January 7, 2004. Therefore, the subject matter added to **Claims 1-21** are considered new matter and must be cancelled from the claims. See *In re Johnson* 558 F. 2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977); *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), *aff'd mem.*, 738 F. 2d 453 (Fed. Cir. 1984); and *Ex parte Parks*, 30 USPQ2d 1234, 1236 (Bd. Pat. App. & Inter. 1993).

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. **Claims 1 and 4** are rejected under 35 U.S.C. 102(b) as being anticipated by Blom et al (4,614,516).

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11. **As to Claim 1**, Blom discloses an implantable surgical apparatus comprising a first flange (18) operable to be placed on the neck of a patient and having an opening therein; a second flange (34) having an opening therein operable to be placed in the trachea of a patient and to secure the surgical apparatus therein; and a shaft (12) having a lumen there through connecting said first and second flange openings, for receiving and securing an oxygen supply line.

12. Examiner notes that Applicant has essentially claimed a statement of intended use. Specifically, in **Claim 1**, Applicant recites, "...operable to be placed on the neck...", "...operable to be placed in the trachea...", and "...for receiving and securing an oxygen supply line". Blom discloses an apparatus in which the claimed functional limitations can inherently be performed since the apparatus of Blom utilizes a flange system that is capable of performing the claimed functional limitations. This recitation is a statement of intended use utilizing functional language, which may not be given weight in apparatus claims. While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function alone. See MPEP§2114.

Therefore as broadly interpreted by the Examiner, the previously presented rejection is applied to **Claim 1** based on the prior art of record.

13. **Claims 1, 5, and 12** are rejected under 35 U.S.C. 102(b) as being anticipated by Bertoch et al (US Publication 2002/0092526).

14. **As to Claims 1, 5, and 12**, Bertoch discloses an implantable surgical apparatus comprising: a first flange (10) operable to be placed on the neck of a patient and having

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an opening therein; a second flange (32) having an opening therein operable to be placed in the trachea of a patient and to secure the surgical apparatus therein; and a shaft (the narrow region between elements 10 and 32) having a lumen (the space occupied by the catheter, element 40) there through connecting said first and second flange openings, for receiving and securing an oxygen supply line; and a catheter (40) inserted into the lumen of the shaft. Specifically in regards to the catheter (40), the broadest reasonable interpretation of the word catheter as described in Stedman's Medical Dictionary (26th edition) is "a tubular instrument to allow the passage of a fluid from or into a body cavity." Therefore, the use of Bertoch's endotracheal tube (40) is essentially a catheter.

15. Examiner notes that Applicant has essentially claimed a statement of intended use. Specifically, in **Claims 1, 5, and 12**, Applicant recites, "...operable to be placed on the neck...", "...operable to be placed in the trachea...", and "...for receiving and securing an oxygen supply line". Blom discloses an apparatus in which the claimed functional limitations can inherently be performed since the apparatus of Blom utilizes a flange system that is capable of performing the claimed functional limitations. This recitation is a statement of intended use utilizing functional language, which may not be given weight in apparatus claims. While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function alone. See MPEP§2114.

Therefore as broadly interpreted by the Examiner, the previously presented rejection is applied to **Claims 1, 5, and 12** based on the prior art of record.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

18. **Claims 2, 3, 13, and 14** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bertoch in view of Sheridan (US Patent 3973569).

19. As to **Claims 2 and 13**, "wherein the first and second flange are offset 90 degrees from one another." These claims are inherently broad and disclose no physical geometry. Therefore, using the broadest reasonable interpretation of **Claims 2 and 13** one can infer that the applicant could be discussing the faces of each flange are inherently offset by 90 degrees. Bertoch is discussed above, yet fail to teach the concept of the flanges or flange faces being offset by 90 degrees. Sheridan discloses a dual flange surgical device formed of flexible, non fibrous plastic (10 and 22). Sheridan device comprises "a fixed flange member (10), a slideable [/rotatable] flange member

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(22), and a plurality of slideable and separately removable ring members (40) positioned between the fixed and slideable flange member" (Please see the abstract). Further Sheridan states, "the second flange member (22) slideably [/rotatably] encircles the tubular section (8)" (Please see Column 2, Lines 44 and 45). Note that this arrangement would enable the flange (22) to be rotated 90 degrees relative to flange (10). Also Sheridan states, "In special cases requiring the greatest depth of insertion, all the ring members (40) as well as the second flange member (22) can be removed leaving only the fixed flange member (10)" (Please see column 3, lines 29-33). In view of the teachings of Sheridan, it would have been obvious to one having ordinary skill in the art at the time of the invention to modify Bertoch to include flange members whose faces and physical geometry are capable of being offset by 90 degrees via the encircling movement around the tubular section of the slideable flange members to aide in the removal and placement of the flanges on the tubular section (8).

20. Moreover, Applicant has not asserted that the specific claimed element recited provides a particular advantage, solves a stated problem or serves a purpose, and thus lacks criticality in its design.

21. Regarding **Claims 3 and 14**, Bertoch is discussed above; yet fail to disclose holes formed in the first flange for affixing the apparatus to the patient. Sheridan discloses slots (18 and 20) in the first flange member (10) as well as slots (30 and 32) on the second flange member (22). Sheridan states, "the flange members have end slots to receive tie tape and the flanges and ring members have aligned holes to provide connection means" (Please see column 2, lines 5-7). However, when the second flange

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(22) and the rings between the first and second flange (40) are removed, the device contains only one flange with slots that can be used attach the flange to the patient (Please see column 3, lines 29-33). In view of the teaching of Sheridan, it would have been obvious to one having ordinary skill in the art at the time of the invention to modify Bertoch to include a end slots located on the flange to provide a connection means and to assist in retaining and maintaining the position of the tracheotomy tube.

22. Examiner notes that Applicant has essentially claimed a statement of intended use. Specifically, in **Claims 3 and 14**, Applicant recites, "...for affixing the apparatus to the patient." Bertoch as modified by Sheridan discloses an apparatus in which the claimed functional limitations can inherently be performed since the apparatus of Bertoch as modified by Sheridan utilizes a flange system that is capable of performing the claimed functional limitations. This recitation is a statement of intended use utilizing functional language, which may not be given weight in apparatus claims. While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function alone. See MPEP§2114. Therefore as broadly interpreted by the Examiner, the previously presented rejection is applied to **Claims 3 and 14** based on the prior art of record.

23. **Claims 4 and 15** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bertoch in view of Tabor (US Patent 4325366).

24. As to **Claims 4 and 15**, Bertoch is discussed above; yet fails to teach the second flange comprising a first and second thickness. Tabor discloses a dual flange (24 and 18) device that is capable of being used with a tracheotomy tube. The base (10) of the second flange (18) "is made of a pliable plastic material such as silicone in order that tubular portion (16) may easily receive valve body (12) inserted into it and flanged portion (18) may easily conform to the paratracheal skin of the patient. A portion (20) of flange (18) can be tapered to facilitate flange (18) conforming to the skin of the patient" (Please see column 2, lines 27-33). The flexibility of the second flange in addition to the second flange's tapered geometry addresses the limitations recited in **Claims 4 and 15**. In view of the teachings from Tabor, it would have been obvious to one having ordinary skill in the art at the time of the invention to modify Bertoch to include a tapered flange to provide a surface where the body of the patient can conform to resulting in a comfortable and tight seal.

25. Examiner notes that Applicant has essentially claimed a statement of intended use. Specifically, in **Claims 4 and 15**, Applicant recites, "...to assist in the implantation of the apparatus." Bertoch as modified by Tabor discloses an apparatus in which the claimed functional limitations can inherently be performed since the apparatus of Bertoch as modified by Tabor utilizes a flange system that is capable of performing the claimed functional limitations. This recitation is a statement of intended use utilizing functional language, which may not be given weight in apparatus claims. While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than

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function alone. See MPEP§2114. Therefore as broadly interpreted by the Examiner, the previously presented rejection is applied to **Claims 4 and 15** based on the prior art of record.

26. **Claims 6, 8, 16, and 18** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bertoch in view of Linder (US Patent 5251617).

27. **As to Claims 6 and 16**, Bertoch discloses an apparatus comprising all the limitations recited in **Claims 6 and 16**, with the exception of a distal end of the shaft including a raised surface to prevent the insertion of said catheter beyond a desired point. However, the use of a raised portion at the end of a shaft was well known at the time the invention was made. Specifically, Linder teaches the use of stop (formed by the shoulder separating bores (34 and 35) to prevent the removal of the connector (31). (Please see Column 4, Line 62 to Column 5, Line 2). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Bertoch by adding a stop because it is well known in the art as taught by Linder to provide an additional safety measure to protect the patient from unintentional harm caused by the catheter being inserted.

28. Examiner notes that Applicant has essentially claimed a statement of intended use. Specifically, in **Claims 6 and 16**, Applicant recites, "...to prevent the insertion of said catheter beyond a desired point." Bertoch as modified by Linder discloses an apparatus in which the claimed functional limitations can inherently be performed since the apparatus of Bertoch as modified by Linder utilizes a flange system that is capable

of performing the claimed functional limitations. This recitation is a statement of intended use utilizing functional language, which may not be given weight in apparatus claims. While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function alone. See MPEP§2114. Therefore as broadly interpreted by the Examiner, the previously presented rejection is applied to **Claims 6 and 16** based on the prior art of record.

29. **As to Claims 8 and 18**, Bertoch discloses an apparatus comprising all the limitations recited in **Claims 8 and 18**, with the exception of a preformed bend in the catheter. However, the use of a preformed bend in a catheter was well known at the time the invention was made. Specifically, Linder teaches the use of a preformed bend to minimize the likelihood of the lumen of the catheter occluding. (Please see Column 4, Lines 45 thru 48). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Bertoch by adding a preformed bend in the catheter because it is well known in the art, as taught by Linder to add an additional safety measure toward patient safety.

30. Moreover, Applicant has not asserted that the specific claimed element recited provides a particular advantage, solves a stated problem, or serves a particular purpose, thus the preformed bend of the catheter lacks criticality in its design.

31. **Claims 9 and 19** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bertoch in view of Muto (US Patent 4246897).

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32. **As to Claims 9 and 19**, Bertoch discloses an apparatus comprising all the limitations recited in **Claims 9 and 19**, with the exception of a beveled end for easing insertion into said shaft. However, the use of a beveled catheter end was known in the art at the time the invention was made. Specifically, Muto teaches the use of a tip (59) that is blunt to not harm the patient's trachea. (Please see Column 3, Line 37-39).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Bertoch by adding a beveled catheter end because it is well known in the art, as taught by Muto to protect the patient's trachea.

33. Examiner notes that Applicant has essentially claimed a statement of intended use. Specifically, in **Claims 9 and 19**, Applicant recites, "...for easing insertion into said shaft." Bertoch as modified by Muto discloses an apparatus in which the claimed functional limitations can inherently be performed since the apparatus of Bertoch as modified by Muto utilizes a flange system that is capable of performing the claimed functional limitations. This recitation is a statement of intended use utilizing functional language, which may not be given weight in apparatus claims. While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function alone. See MPEP§2114. Therefore as broadly interpreted by the Examiner, the previously presented rejection is applied to **Claims 9 and 19** based on the prior art of record.

34. **Claims 7 and 17** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bertoch in view of Arkinstall (US Patent 5287852).

35. **As to Claims 7 and 17**, Bertoch is discussed above; yet fails to teach the concept of adding a bushing or washer larger in diameter than the lumen. Arkinstall discloses a tracheal apparatus that contains a bushing conduit (12) and a washer (14). The washer "enables the wall to be squeezed over a continuous range of forces which enables the apparatus to be installed securely, yet comfortably on the tracheostomy patient" (Please see column 3, line 55 –59). The bushing conduit (12) is "removably secured to the patient's neck. The unobstructed coterminous opening in the conduit permit the insertion of a cuffed endotracheal tube to provide an airtight seal in the trachea to allow for mechanical ventilation, allows easy access of suction catheter to clear retained secretions, and enables a plug or other device to seal the ventilation opening to allow for near normal ventilation to and from the trachea via the oropharynx , with out compromising the engagement of the retaining means with the anterior tracheal wall and with out appreciably compromising air flow the trachea" (Please see column 4, line 3-14). In view of the teachings of Arkinstall, it would have been obvious to one having ordinary skill in the art at the time of the invention to modify Bertoch to include a bushing where in the diameter of the bushing is larger than that of the lumen to provide a method of maintaining the tracheal stoma with out compromising the patient's air flow.

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36. **Claims 10 and 20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bertoch in view of Miller (US Patent 3659611) and further in view of Kolobow (US Patent 5305740).

37. **As to Claims 10 and 20**, Bertoch is discussed above, yet fails to teach the first and second flanges being opposedly curved. Miller discloses a tracheal tube seal consisting of "a series of thin, solid, resilient, disc-like flanges (18, 19, and 20) preferably attached to the tubular portion (12) in spaced parallel relationships perpendicular to the axis of the tubular portion" (Please see column 2, lines 13-16). Seen below is Figure 2 of the Miller patent showing the device inserted into the patient.

Patented May 2, 1972

3,659,611

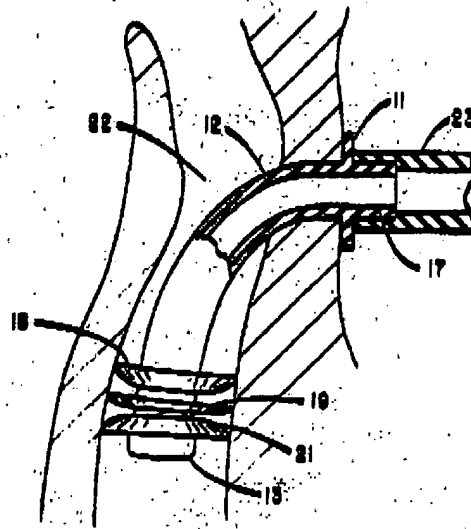


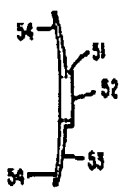
Fig. 2

38. As seen above, the flanges (18 and 21) have become opposedly curved as a result of the flexible nature of the material used to create the flanges and insertion into the patient's trachea. Regarding the middle flange (19), Miller teaches that a choice

when designing the number of flanges that are incorporated into a tracheal device.

(Please see column 2, lines 32-33). It would have been obvious to one having ordinary skill in the art to modify the tracheal system of Bertoch to have provided a dual or multiple flange system for the purpose of creating a tight seal between the tracheal device and the patient's trachea.

39. The combination of Bertoch as modified by Miller; however, does not show or teach an insertion method for creating the opposedly curved flanges from multi-flanged systems. Kolobow teaches a sealing means for endotracheal tubes incorporating multiple flange system using flanges (53) with tapered edges as seen in below in figure 6B of the Kolobow patent. Kolobow states "when the tubular member having curved



gills or flanges (53) is first inserted then backed out a short distance to reverse the curve of the gills or flanges (53) from the direction in which they are oriented when being inserted. In this embodiment, the curve

FIG. 6B

shape can provide a small bias force to the seal means" (Please see

column 9, line 17-21). It would have been obvious to one of ordinary skill in the art to have modified the tracheal system of Bertoch as modified by Miller to have provided an insertion method for creating the opposedly curved flanges from multi-flanged systems as taught by Kolobow for the purpose of creating a tight seal between the tracheal device and the patient's trachea.

40. Moreover, Applicant has not asserted that the specific claimed element recited provides a particular advantage, solves a stated problem, or serves a particular purpose, and thus lacks criticality in its design.

41. **Claims 11 and 21** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bertoch in view of Thomas (US Patent Publication: US 2005/0166924 A1).

42. **As to Claims 11 and 21**, Bertoch is discussed above; yet fails to teach the concept of the flanges having different values of durometer hardness. Thomas discloses a multiple cannula system for a tracheostomy tube assembly. The cannula system where, “the substantially rigid tip portion being made with a rigid PVC material having a shore D hardness of between 55 to 65 and the substantially flexible portion being made with a flexible PVC material having a shore A hardness of between 80 to 90” (Please see paragraph 11). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the tracheal system of Bertoch to have incorporated structural elements at different hardness values as taught by Thomas for the purpose of providing the necessary level of durability for structures that are exposed to different environmental forces and elements.

43. The specific hardness values are noted; however, from a close reading of the specification there is no criticality disclosed for the actual hardness values of about 70 for the first flange and of about 50 for the second flange. Therefore, one of ordinary skill in the art at the time of the invention would find it obvious to construct the flanges to the claimed hardness values or any other hardness values that are suitable to the procedure that is being administered on the patient.

Conclusion

44. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette F. Dixon whose telephone number is (571) 272-3392. The examiner can normally be reached on Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



AFD
March 23, 2006



Henry Bennett
Supervisory Patent Examiner
Group 3700